

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Arthritis Advisory Committee (AAC) Meeting
May 6, 2021

AGENDA

The committee will discuss New Drug Application (NDA) 214487, for avacopan oral capsules, submitted by ChemoCentryx, Inc., for the treatment of Anti-Neutrophil Cytoplasmic Antibody (ANCA)-associated Vasculitis.

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| 10:00 a.m. | Call to Order | Mara L. Becker, MD, MSCE
Chairperson, AAC |
| 10:10 a.m. | Introduction of Committee and Conflict of Interest Statement | Moon Hee V. Choi, PharmD
Acting Designated Federal Officer, AAC |
| 10:15 a.m. | FDA Opening Remarks | Rachel L. Glaser, MD
Clinical Team Leader
Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation
Office of New Drugs, CDER, FDA |
| 10:20 a.m. | APPLICANT PRESENTATIONS | ChemoCentryx, Inc. |
| | Introduction | Pirow Bekker, MD, PhD
Clinical Lead
Avacopan Clinical Development Program
ChemoCentryx, Inc. |
| | Efficacy | Peter Merkel, MD, MPH
Chief, Division of Rheumatology
Director, Penn Vasculitis Center
University of Pennsylvania |
| | Safety | David Jayne, MD
Professor of Clinical Autoimmunity
University of Cambridge, United Kingdom
Director, Vasculitis and Lupus Service
Addenbrooke's Hospital
President, European Vasculitis Society (EUVAS) |
| 10:50 a.m. | Clarifying Questions for Applicant | Pirow Bekker, MD, PhD |

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AGENDA (cont.)

11:20 a.m. **FDA PRESENTATION**

FDA Summary Presentation

Rachel L. Glaser, MD

11:45 a.m. Clarifying questions for FDA

12:15 p.m. **LUNCH BREAK**

1:15 p.m. **OPEN PUBLIC HEARING**

2:15 p.m. Charge to the Committee

Rachel L. Glaser, MD

2:20 p.m. Questions to the Committee/Committee
Discussion

4:15 p.m. **ADJOURNMENT**